

## REMARKS

Claims 11, 20 and 30 have been amended. Claims 1 - 10, 13 and 15 have been canceled. Claims 22 - 29 have been withdrawn. No new matter has been added. Thus, claims 11, 12, 14, 16 - 30 remain pending in the present application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Applicants hereby confirm the election of Group I corresponding to claims 11, 12, 14, 16 - 21 and 30. Claims 22 - 29 have been withdrawn from further consideration.

Claim 12 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In support of the rejection, the Examiner argues that the term “substantially octagonal” is unclear. It appears that the Examiner has intended to reject claim 20, which is directed to an octagonal shape of the ball joint. Claim 20 has been amended to remove the term “substantially” and now recites a bone screw “wherein the ball has an octagonal shape.” In light of the amendment, it is respectfully requested that the rejection of claim 20 be withdrawn.

Claims 11 - 14, 16 - 18, 21 and 30 stand rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 6,375,684 to Kriek.

Amended claim 11 recites a bone screw comprising “*a head having a first outer diameter, and a cannulated shaft having a longitudinal axis, the cannulated shaft further comprising a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter, an outer wall of the proximal section being at least partially threaded, and a distal section attached to the proximal section by way of a ball-and-socket joint.*”

It is respectfully submitted that Kriek fails to teach or suggest “*a cannulated shaft,*” as recited in amended claim 1. Rather, Kriek teaches a hip prosthesis formed without a cannula

extending therethrough. It is further noted that the present invention is directed to a cannulated shaft which permits insertion of the bone screw over a Kirschner wire used to aid in the positioning and drilling of a bore through the bone. (See Specification, ¶ [0022], [0025] - [0029]). The device of Krick, on the other hand, uses both X-ray guidance and a drill jig M to aid in positioning and drilling a bore through the bone F. (See Krick, col. 5, li. 65 - col. 6, li. 27; Figs. 1 - 15). Furthermore, the prosthesis of Krick is configured to be used in combination with a hollow tube 19 through which a drilling tool 20 and ultimately, the hip prosthesis are inserted to their target positions relative to the bone. (*Id.*). It is therefore respectfully submitted that Krick further teaches away from the limitation of “a cannulated shaft,” as recited in amended claim 11, since such an embodiment would serve no useful purpose in the device of Krick.

It is therefore respectfully submitted that Krick fails to teach or suggest “a *cannulated shaft*,” as recited in claim 11 and that claim 11 is therefore in condition for allowance. Because claims 12, 14, 16 - 18 and 21 depend from and therefore include all of the limitations of claim 11, it is respectfully submitted that these claims are also allowable.

Amended claim 30 recites limitations substantially similar to claim 11, including a bone screw comprising “a head, *a cannulated shaft* having a longitudinal axis, a proximal section adjoining the head wherein the proximal section is at least partially threaded, and a distal section polyaxially associated with the proximal section.” It is therefore respectfully submitted that claim 30 is allowable over Krick for the same reasons noted above with respect to claim 11.

Claims 11 and 18 - 19 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,887,242 to Doubler et al. (hereinafter “Doubler”).

It is respectfully submitted that Doubler fails to teach or suggest a bone screw comprising “a *cannulated shaft* having a longitudinal axis, the cannulated shaft further comprising *a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter, an outer wall of the proximal section being at least partially threaded,*” as

recited in claim 11. Rather, Doubler is directed to a toggle bolt 22 having a threaded end 42, which the Examiner analogizes to the “head” of claim 11 and a tapered end 40 over which a retention ring 24 is fitted. (See Doubler, col. 6, li. 53 - col. 7, li. 4; Figs. 2 - 5). It is first noted that Doubler fails to teach a “cannulated shaft,” as recited in claim 11 and that claim 11 is allowable over Doubler for at least this reason. In support of the rejection, the Examiner also analogizes the portion of the pedicle screw 20 located between the threaded head 42 and the tapered end 40 to the “proximal section” of claim 11. (See 8/18/09 Office Action, p. 6). However, it is respectfully submitted that this portion of the pedicle screw 20 does not meet the limitation of “*an outer wall of the proximal section being at least partially threaded,*” as recited in claim 11. Rather, this portion of the pedicle screw 20 is formed with a smooth outer surface. It is respectfully submitted that claim 11 is allowable over Doubler for at least this additional reason.

Still further, it is respectfully submitted that Doubler fails to teach “a distal section attached to the proximal section by way of a ball-and-socket joint,” as recited in claim 11. Rather, Doubler teaches a toggle bolt 22 having retention ring provided over a tapered end 40. (See Doubler, col. 6, li. 53 - 64; Figs. 3 - 5). It is respectfully submitted that the fitting of the ring 24 over the tapered end 40 does not meet the limitation of a “ball” as recited in claim 11. Specifically, the ring 24 in no way resembles a “ball” since it is merely a ring having a circular cross-section. A ball of a “ball-and-socket” joint, on the other hand, is understood by those of skill in the art as a joint having a substantially spherical element configured to be received within a respectively shaped socket. (See Specification, ¶ [0006]). It is noted that although the term “spherical” is not used within the claim, this limitation is inherent within the term “ball-and-socket” as would be understood by one of skill in the art. It is therefore respectfully submitted that Doubler also fails to teach or suggest “a distal section attached to the proximal section by way of a ball-and-socket joint,” as recited in claim 11 and that claim 11 is allowable for at least this additional reason.

It is therefore respectfully submitted that Doubler fails to teach or suggest “*a cannulated*

*shaft* having a longitudinal axis, the cannulated shaft further comprising a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter, *an outer wall of the proximal section being at least partially threaded, and a distal section attached to the proximal section by way of a ball-and-socket joint,*” as recited in claim 11 and that claim 11 is therefore in condition for allowance. Because 18 - 19 depend from and therefore include all of the limitations of claim 11, it is respectfully submitted that these claims are also allowable.

Claims 11 and 15 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2004/0143265 to Landry et al. (hereinafter “Landry”).

Landry fails to teach or suggest “*a head having a first outer diameter, and a cannulated shaft having a longitudinal axis, the cannulated shaft further comprising a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter, an outer wall of the proximal section being at least partially threaded, and a distal section attached to the proximal section by way of a ball-and-socket joint,*” as recited in claim 11. In support of the rejection, the Examiner analogizes the closure members 106 of Landry to the “head” of claim 11 and the collar 112 of Landry to the “proximal section” of claim 11. (See 8/18/09 Office Action, pp. 6 - 7). However, it is respectfully submitted that the closure members 106 fail to meet the limitation of “a head having a first outer diameter” and “a proximal section...having a second outer diameter smaller than the first outer diameter,” as recited in amended claim 11. Rather, the collar 112 of Landry has a larger diameter than the closure member 106 since the closure member 106 is received within the collar 112 to form a joint therewith. (See Landry, ¶ [160]; Figs. 1 - 2).

It is therefore respectfully submitted that the closure members 106 fail to meet the limitation of “a head having a first outer diameter” and “a proximal section...having a second outer diameter smaller than the first outer diameter,” as recited in claim 11 and that claim 11 is therefore in condition for allowance.

Claims 11 and 20 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2004/0236330 to Purcell et al. (hereinafter “Purcell”).

Purcell fails to teach or suggest “a head having a first outer diameter, and a cannulated shaft having a longitudinal axis, *the cannulated shaft further comprising a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter, an outer wall of the proximal section being at least partially threaded,*” as recited in claim 11. In support of the rejection, the Examiner analogizes a proximal end of the body member 14 of Purcell to the “head” of claim 11 and distal portion of the body member 14 of Purcell to the “proximal section” of claim 11. (*See* 8/18/09 Office Action, p. 7). However, it is respectfully submitted that the body member 14 is formed with a uniform outer diameter and thus fails to meet the limitation of “a head having a first outer diameter” in combination with “a *proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter,*” as recited in claim 11. Rather, Purcell makes no disclosure with respect to the outer diameter of the body member 14. It is evident, however, from the drawings, that the body member 14 has a uniform outer diameter and thus fails to meet the limitations of a “head having a first outer diameter” and a proximal section “having a second outer diameter smaller than the first outer diameter,” as recited in amended claim 11. (*See* Purcell, Figs. 1, 3A, 3B, 4, 8). It is submitted that claim 11 is allowable over Purcell for at least this reason.

Furthermore, it is respectfully submitted that Purcell fails to teach or suggest “*an outer wall of the proximal section being at least partially threaded,*” as recited in claim 11. Rather, Purcell does not teach any threading formed on an outer wall of the body member 14 at all. It is therefore respectfully submitted that claim 11 is allowable over Purcell for at least this additional reason.

It is therefore respectfully submitted that Purcell fails to teach or suggest “a head having a first outer diameter, and a cannulated shaft having a longitudinal axis, *the cannulated shaft further comprising a proximal section adjoining the head and having a second outer diameter*

*smaller than the first outer diameter, an outer wall of the proximal section being at least partially threaded,”* as recited in claim 11 and that claim 11 is in condition for allowance. Because claim 20 depends from and therefore includes all of the limitations of claim 11, it is respectfully submitted that this claim is also allowable.

In view of the remarks submitted above, the Applicants respectfully submit that the present case is in condition for allowance. All issues raised by the Examiner have been addressed, and a favorable action on the merits is thus earnestly requested.

Respectfully submitted,

Dated: November 17, 2009

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